REMARKS

I. Status of the Claims

Claims 32, 34, 35, 38, 42, 43, 45-48, 50, and 59-64 are pending in this application. Claim 49 is cancelled, and claims 59-61, and 64 are amended herein. Applicants amended claims 59-61 and 64 to correct typographical errors in the concentration units for BDE 47: Claims 59-61 are amended to recite "12.2 ng/g" with support in Figure 2 (2,2'4,4'-TetBDE, IUPAC No. BDE-47), and claim 64 is amended to recite "5.3 μg/kg" with support in Example 6, Table 5 on page 30 of the specification. No new matter is added.

Applicants also amended the specification to include Figure 2 as described in page 29 (Example 5). Accordingly, no new matter is added by any of the amendments herein.

Applicants thank the Examiner for allowing claims 47-50 and 59. Office Action at pages 2 and 5. Applicants note that those claims were also listed among the rejected claims. *Id.* at 2. In view of the Office's explicit allowance, Applicants assume that claims 47-50 and 59 stand allowed. *Id.* at 5.

Applicants also thank the Examiner for withdrawing the rejection under 35 U.S.C. § 102(b) over Dam et al.

II. Rejections Under 35 U.S.C. § 112, 1st Paragraph

The Office maintains the rejection of claims 32, 34, 35, 38, 42, 43, 45-50, and 59-64 under 35 U.S.C. § 112, 1st paragraph, as allegedly failing to comply with the written description requirement. *Id.* at 2. Applicants note that claims 47-50 and 59 are allowed.

Id. at 5. Thus, Applicants respectfully continue to disagree and traverse the rejection of claims 32, 34, 35, 38, 42, 43, 45, 46, and 61-64.

The Office has acknowledged possession, but asserts that "being in possession of the invention is not in question but how to use the invention. . . . The written description for the 'pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia' [recited in the claims] is not present." *Id.* at 3. Applicants continue to respectfully disagree and traverse the rejection.

Page 15, lines 6-11 (emphasis added) of the specification expressly provides that "[i]n [a] more preferred embodiment of the invention, the **pharmaceutical** and/or health supplement **comprises at least one of EPA/DHA ethyl esters and is intended for** a range of potential **therapeutic** applications including; **treatment of hypertriglyceridaemia**...." Accordingly, the present application provides written description support for the claimed composition.

Applicants respectfully submit that the Office mistakenly rejected the claims for lack of written description. *See* Office Action at 3 (emphasis added) ("As stated previously, **being in possession of the invention is <u>not</u> in question <u>but how to use the invention</u>**."). Use of the invention is a question of enablement. M.P.E.P. § 2164. The test for enablement is whether one of ordinary skill in the art could have made and used the claimed invention without undue experimentation. Applicants' specification provided sufficient guidance to do so.

Furthermore, "it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation." M.P.E.P. § 2164.01(c). The present specification provides that "the

term 'treating' means both treatment having a cur[]ing or alleviating purpose and treatment having a preventive purpose. The treatment can be made either acutely or chronically." Specification at page 21, lines 5-9. The skilled artisan, familiar with pharmacological arts and in view of Applicants' disclosure, would be able to provide a the "pharmaceutically effective concentration" presently claimed.

The term "effective amount" is commonly employed and its meaning well recognized in the art. *See, e.g., Abbott Labs. v. Baxter Pharmaceutical Prods., Inc.*, 334 F.3d 1274, 1278-79, 67 U.S.P.Q.2d 1191, 1194-95 (Fed. Cir. 2003) ("[T]his court notes that the term 'effective amount' has a customary usage"); *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1375, 1383-84, 68 U.S.P.Q.2d 1865, 1873 (Fed. Cir. 2003) ("Our predecessor court has stated that 'effective amount' is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation"). Here, one of ordinary skill in the art would be aware of the amount of the claimed composition effective for treatment, wherein the content of EPA and/or DHA is achieved by the reduction of various pollutants. *See* Applicants' specification at page 14, ll. 20-36.

In addition, the Federal Circuit has held that, when an "effective amount" is not set forth in the intrinsic evidence, it is proper to resort to extrinsic evidence to determine what one of ordinary skill in the art at the time the application was filed would consider to be an "effective amount" may be relied upon. *See, e.g., Key Pharmaceuticals v. Hercon Laboratories Corp.*, 161 F.3d 709, 718, 48 USPQ2d 1911, 1918 (Fed. Cir. 1998) (proper for district court to rely on FDA guidelines existing at the time the application

was filed to determine the amount of nitroglycerin needed to be delivered by the claimed patch in interpreting the limitation "to deliver to the skin a pharmaceutically effective amount of said pharmaceutically active drug" limitation, where the specification did not disclose what was considered to be a "pharmaceutically effective amount").

In the present case, the use of 4 grams per day of Omacor® (now called Lovaza™) as a **pharmaceutical**, was approved by the FDA in November 2004 (i.e., before the filing of the present application) to be used as an adjunct to diet to reduce very high (~ 500 mg/dL) triglyceride (TG) levels in adult patients. Also prior to the filing of the present application, the FDA had issued qualified health claims for **dietary supplements** containing omega-3 fatty acids in 2000 and for **conventional foods** containing the same in 2004 *(see., e.g.,* FDA news dated September 8,2004, already of record). Therein, the FDA expressly recommended that "consumers not exceed more than a total of 3 grams per day of EPA and DHA omega-3 fatty acids, with no more than 2 grams per day from a **dietary supplement**." *Id.* (emphasis added). Accordingly, one of ordinary skill in the art would have recognized, at least from FDA guidelines, would have understood what "a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia" was.

The Office further asserts that "applicant's arguments regarding the amounts given for various pollutants such as PCDD, PCDF & TE PCB not being disclosed in the specification . . . [have] no merit." Office Action at 3. Yet, the Office does not provide any reason for dismissing Applicants' arguments of September 16, 2008, made in response to the previous Office Action. And the Office allowed claims 47-50 and 59,

which recite pollutant concentrations. *Id.* at 5. Nonetheless, Applicants once again direct the Office to support for the claimed concentrations as follows:

Claimed concentration	Support in specification	Claims
"less than 0.2 μg/kg as measured by the concentration of BDE 47"	Example 6, Table 5 at page 30 5.3 μg/kg before treatment; **< 0.2 μg/kg after distillation**	32, 34, 35, 43, 47-50, 62
"the concentration of BDE 47 in the marine oil is less than 12.2 ng/g"	Figure 2 **12.2 ng/g before stripping**; 0.58 ng/g after stripping	59-61
"the sum of PCDDs and PCDFs in the marine oil is less than 4.65 pg/g"	Figure 2 **4.65 pg/g before stripping**; 0.46 pg/g after stripping	34
"the sum of TE-PCBs in the marine oil is less than 22.6 pg/g"	Figure 2 **22.6 pg/g before stripping**; 0.09 pg/g after stripping	35, 38, 46, 50
"the sum of PCDDs and PCDFs in the marine oil is 0.46 pg/g or between 0.46 pg/g and 4.65 pg/g"	Figure 2 **4.65 pg/g before stripping; 0.46 pg/g after stripping**	62
"the concentration of BDE 47 in the marine oil is less than 5.3 μg/kg"	Example 6, Table 5 at page 30 **5.3 μg/kg before treatment**; < 0.2 μg/kg after distillation	64

As shown above, and in Applicants' previous response, the pollutant concentrations recited in the present claims are supported by the specification. The Office bears the burden of presenting express findings of fact to establish a *prima facie* case of lack of written description, and to maintain that rejection in view of an applicant's rebuttal arguments. M.P.E.P. § 2163.04. The Office does not provide those required findings of fact in this case. Applicants respectfully submit that the Office fails to establish lack of written description, and request that the rejections be withdrawn.

III. Rejection Under 35 U.S.C. § 102(b)

The Office rejects claims 32, 34, 35, 38, 42, 43, 45, 46, and 60-64 under 35 U.S.C. § 102(b) as allegedly anticipated by the product specifications for EPAX 4020EE, 5500EE, 6000EE, or 6010EE. Office Action at page 4. Applicants respectfully continue to disagree and traverse the rejection.

The Office asserts, based on M.P.E.P. § 2107.01, that "[t]he fact that the FDA has made certain determinations regarding health supplements has no weight regarding the patentability of the instant invention." *Id.* Applicants disagree.

First, M.P.E.P. § 2107.01 relates to the utility requirement under 35 U.S.C. § 101, rather than a determination with respect to a prior art reference.

Furthermore, the Office mischaracterizes that section. M.P.E.P. § 2107.01, citing *In re Brana*, 51 F.3d 1560, 1568, 34 U.S.P.Q.2d 1436, 1442-43 (Fed. Cir. 1995), provides that "**FDA approval . . . is not a prerequisite** for finding a compound useful within the meaning of patent laws" (emphasis added). Thus, § 2107.01 merely provides that FDA requirements may not impose stricter criteria to patentability than do the patent laws. Nowhere does the M.P.E.P., or any patent law for that matter, prohibit the use of FDA approval or guidelines as probative evidence of what one of ordinary skill in the art would have known at the relevant time.

The present claims recite a pharmaceutical that is not a health supplement. *See, e.g.*, claim 32. As Applicants previously discussed, the FDA has approved the use of 4 grams per day of Lovaza™ (comprising about 465 mg DHA and 375 mg EPA per 1 gram capsule), but recommends no more than 2 grams per day from a dietary supplement. *See* Lovaza label and FDA news dated September 8, 2004 (documents of

record). The EPAX product specifications expressly disclose that they are health supplements, which fail to anticipate the present claims under § 102(b).

Further, Applicants did not state that EPAX products do not comprise marine oil, as the Office asserts. Office Action at page 4. Rather, Applicants explained that the EPAX products do not comprise a marine oil comprising **EPA and DHA in a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia**, as recited in the present claims.

The Office asserts that "[i]f the prior art structure is capable of performing the intended use, then it meets the claim." Office Action at page 5. Intended use for matters of claim construction relates to the preamble of a claim, which does not apply for the present claims. *See* M.P.E.P. § 2111.02. The Federal Circuit has stated that "when the claim drafter chooses to use *both* the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." *Id.*, *citing Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 U.S.P.Q.2d 1816, 1820 (Fed. Cir. 1995) (emphasis original). *See also Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1340, 66 U.S.P.Q.2d 1271, 1277 (Fed. Cir. 2003) (structural components recited in method claim preamble treated as limitations where the structure, as recited in the preamble, provided antecedent basis for specific steps recited in body of claim). And, even in the case of a preamble limitation, the M.P.E.P. provides that "a preamble may provide context for claim construction, particularly, where . . . that preamble's statement of intended use forms that basis for distinguishing the prior art in the patent's prosecution history." M.P.E.P. § 2111.01 (*citing Metabolite Labs., Inc. v. Corp. of Am. Holdings*, 370

F.3d 1354, 1358-62, 71 U.S.P.Q. 1081, 1084-87 (Fed. Cir. 2004). The EPAX product specifications disclose health supplements, thus failing to teach each and every limitation of the present claims as required for a rejection under § 102(b).

For at least the foregoing reasons, none of the EPAX products or their specifications anticipate the present claims. Accordingly, Applicants respectfully request that the Office withdraw the rejections.

IV. Conclusion

Applicants respectfully request that the amendments herein be entered by the Office and request reconsideration and allowance of the present claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 27, 2009

By:_____
Jill K. MacAlpine
Reg. No. 60,475
(202) 408-4000